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REMARKS

This paper is in response to the Final Office action mailed August 15, 2006. Upon entry of the instant amendment, claims 31-45, 48, 67, 68 and new claims 69-72 are pending.

I. Allowable Subject Matter

Applicants thank the examiner for acknowledging that claims 35, 45, 46 and 48 are free of the prior art and may be considered allowable if rewritten in independent form to include all the limitations of the base claims. By this amendment, new claim 69 has been added and includes the subject matter of original claims 31 and 33-34. Moreover, new claims 70-72 correspond to original claims 45, 46 and 48, respectively. Applicants submit that no new matter has been added, and based upon the Examiner's comments regarding the allowability of claims 35, 45, 46 and 48 and the amendments made herein, new claims 69-72 and all claims dependent thereon should be in condition for allowance.

II. The Rejection Under 35 U.S.C. § 102(b) May Properly Be Withdrawn.

The examiner rejected claims 31-34, 42, 43 and 67-68 under 35 U.S.C. § 102(b) as allegedly being anticipated by Saito et al., Proc. Natl. Acad. USA, 92:10227-10231, 1995 (hereinafter "Saito"). In the action, the examiner states that "the specification encompasses any non-Aβ polypeptides with a preference on those that are useful in diagnosis or treatment of CNS but with no exclusiveness to any particular ones."

In response, claim 31 has been amended to recite "wherein said composition is for treating a human patient that has been diagnosed with a CNS disorder." Support for the amendment can be found, for example, at page 12, line 9, of the specification.

As indicated in the response to the previous Office action, Saito discloses a composition comprising a vector-mediated drug delivery system composed of a conjugate of $A\beta^{1-40}$, streptavidin, biotin and the OX26 monoclonal antibody to the transferrin receptor, wherein the OX26 monoclonal antibody is intended to deliver the composition across the blood brain barrier (BBB). See page 10227, 2nd column, lines 2-5 and Figure 1. However,

Saito teaches that its delivery system is used for neuroimaging Aβ amyloid plaques. Saito provides no disclosure for the treatment of any subject that has been diagnosed with a CNS disorder, let alone a human patient as recited in claim 31. Anticipation requires that the cited art disclose each and every element of the claims, which is not the case here. In view of the foregoing, applicants respectfully request that the rejection of claims 31-34, 42 and 43 under 35 U.S.C. §102(b) be withdrawn.

Further, it appears that the examiner did not respond to the applicants' argument with respect to claims 67-68. As discussed in the response to the previous Office action, Saito cannot provide the basis for an anticipation rejection for new claims 67-68 because Saito does not teach that the Aβ polypeptide is covalently linked to a non-Aβ polypeptide. Accordingly, Saito does not disclose each and every element of the claims and therefore cannot destroy the novelty of claim 67 and those claims dependent thereon. In view of the foregoing, applicants respectfully request that the rejection of claims 67-68 under 35 U.S.C. §102(b) be withdrawn.

III. The Rejection of Claim 44 Under 35 U.S.C. § 103(a) May Properly Be Withdrawn.

The examiner rejected claim 44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saito. The examiner asserts that "it would have been *prima facie* obvious to a person of ordinary skill in the art to use Aβ 1-42 polypeptide to construct the molecule as disclosed by Saito."

Claim 44 depends indirectly from claim 31, which requires that the composition is for treating a human patient that has been diagnosed with a CNS disorder. As discussed in the previous section, Saito does not teach or suggest linking an Aβ polypeptide to non-Aβ polypeptide for treating a human patient that has been diagnosed with a CNS disorder, but rather suggests the use of OX26 monoclonal antibody to deliver Aβ polypeptide for neuroimaging the Aβ amyloid plaques. Further, Saito provides no disclosure for the treatment of any subject that has been diagnosed with a CNS disorder, let alone a human patient as recited in claim 31.

Even if, assuming for the purposes of argument, the delivery system of Saito were to be used to deliver a therapeutic agent, then Saito's teaching would lead one of ordinary skill in the art to link OX26 monoclonal antibody (which is the delivery agent) to a different therapeutic agent, and therefore completely remove Aβ from the delivery system.

Accordingly, Saito fails to teach or suggest all of the limitations of the claims (e.g., composition for treating a human patient that has been diagnosed with a CNS disorder) and there is no teaching or suggestion in Saito that a composition comprising an Aβ polypeptide linked to a non-Aβ polypeptide can be used to treat a human patient that has been diagnosed with a CNS disorder. Therefore, in view of Saito's failure to teach or suggest the claimed invention, applicants respectfully submit that the claims are novel and inventive over Saito, and reconsideration and withdrawal of the rejection is respectfully requested.

IV. The Rejection of Claims 36-40 and 49-50 Under 35 U.S.C. § 103(a) May Properly Be Withdrawn.

The examiner rejected claims 36-40 and 49-50 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saito in view of Solomon et al., (WO 99/60024). The examiner asserts that "it would have been obvious to a person of ordinary skill in the art to modify chimeric polypeptide of Saito to include fragments or chimeric antibodies in the construct, or to label the antibody." Applicants respectfully disagree with the examiner's assertion and request reconsideration in view of the following remarks.

One of ordinary skill in the art would not have been motivated to substitute the anti-amyloid antibodies disclosed by Solomon for the OX26 monoclonal antibody in the conjugate disclosed in Saito because the OX26 antibody is required as the delivery agent. To the extent that the examiner cites Solomon for its disclosure of "fragments or chimeric antibodies . . . or to label the antibody," such a modification of the OX26 monoclonal antibody of Saito does not teach or suggest the invention recited in claims 36-40, which is a composition comprising an Aβ polypeptide linked to a non-Aβ polypeptide for treating a human patient that has been diagnosed with a CNS disorder. Accordingly, no combination of Saito and Solomon teaches or suggests all of the limitations of the claims and the rejection may properly be withdrawn.

V. The Rejection of Claim 41 Under 35 U.S.C. § 103(a) May Properly Be Withdrawn.

The examiner rejected claim 41 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Saito in view of Poduslo (U.S. Patent No. 5,670,477). The examiner asserts that "it would have been obvious to a person of ordinary skill in the art to conjugate a molecule intended for delivery through blood-brain-barrier to a polyamine as disclosed in '477 patent. One of ordinary skill in the art would have been motivated to do so because '477 patent specifically teaches the advantages of linking polyamine to a compound to be delivered to the brain." Applicants respectfully disagree with the examiner's assertion and request reconsideration in view of the following remarks.

Saito and Poduslo are improperly combined because the examiner has not shown where there is a teaching in either reference or any motivation to combine references that each teach a different method for enhancing delivery across the blood brain barrier, nor has the examiner shown a reasonable expectation that combining polyamine modification with OX26 monoclonal antibody-based delivery would meet with success. One of ordinary skill would have thought it possible that polyamine modification of the OX26 monoclonal antibody could reduce its ability to transport across the blood brain barrier.

Moreover, as discussed above in Sections II and III, Saito does not teach or suggest the claimed composition and therefore cannot provide the basis for an obviousness rejection for any of the pending claims. Poduslo, which teaches modification of a compound by conjugating it to a polyamine, fails to provide the disclosure lacking from Saito. Accordingly, no combination of Saito and Poduslo teaches or suggests all of the limitations of the claims (e.g., composition for treating a human patient that has been diagnosed with a CNS disorder) and there is no teaching or suggestion in either Saito or Solomon that a composition comprising an Aβ polypeptide linked to a non-Aβ polypeptide can be used to treat a human patient that have been diagnosed with a CNS disorder. Therefore, no combination of these references teaches or suggests the compositions as recited in the claims. Accordingly, applicants respectfully submit that claim 41 is novel and inventive over Saito in view of Poduslo and the rejection may properly be withdrawn.

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VI. Conclusion

It is believed that the foregoing responds to all of the examiner's concerns. If the examiner believes that a telephone conversation would expedite allowance of the claims, she is invited to contact the undersigned agent or Li-Hsien Rin-Laures, attorney for applicants, at the number below.

The Director is hereby authorized to charge any fees associated with the filing of this paper to Deposit Account No. 13-2855, under order no. 01017/30016A.

Dated: October 17, 2006

Respectfully submitted,

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